IN THE CLAIMS

1 (currently amended): A drug delivery regimen, which comprises:

an active therapeutic substance(s) selected from the group consisting of ~~anti-hypertensive agents, osteoporotic agents, GERD agents, anti-viral agents, anti-neoplastic agents, inhaled steroids, lipid lowering agents, thrombolytic agents, anticoagulant agents, fibrinolytic agents, anti-asthmatics, hormone replacement agents, anti-infectives, anti-diabetics,~~ vitamins, ~~herbal agents,~~ minerals~~, fatty acids, electrolytes~~ and combinations thereof administered multiple times during at least one 24 hour period of time to provide effective therapeutic levels of the active therapeutic substance (s) at a site or sites of action in an animal over said period, wherein each individual dose is independently adjusted to be administered to optimize levels of the active therapeutic substance(s) at the site or sites of action for maximum efficacy, and wherein the dose amount at each administration is independently characterized by the formula TD(t) = CD(t) + RD(t), where t is the time at which the dose is to be administered, TD (therapeutic dose) is the therapeutically effective dose at time (t), CD (current dose) is the dose to be administered at time (t), and RD (residual dose) is the amount of active therapeutic substance(s) remaining from the previous dose administration.

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239 ~~2~~. (new): The drug delivery regimen of claim 1, wherein the vitamin is selected from the group consisting of thiamine, niacinamide, pyridoxine, ascorbic acid, riboflavin, folic acid, vitamin A, vitamin E, vitamin D3, cyanocobalamin, biotin, pantothenic acid, derivatives thereof, and combinations thereof.

240 ~~3~~. (new): The drug delivery regimen of claim 1, wherein the mineral is selected from the group consisting of copper, zinc, iodide, magnesium, chromium, molybdenum, sodium, calcium, iron, fluoride, phosphorus, manganese, potassium, boron, selenium, bioflavonoid, phosphate, derivatives thereof and combinations thereof.

241 ~~4~~. (new): The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is administered to increase efficacy.

242 ~~5~~. (new): The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is administered to reduce the total dosage administered per day while maintaining equivalent efficacy.

243 ~~6~~. (new): The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is administered to minimize incidents of side effects.

244
~~7~~ (new): The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is administered to improve patient compliance with the drug delivery regimen.

245
~~8~~ (new): The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is administered to improve convenience of administration.

246
~~9~~ (new): The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is administered at least once and may be administered as immediate release, sustained release, controlled release, delayed release, timed release, extended release, or any combination thereof.

247
~~10~~ (new): The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is administered by pulsatile delivery of the active therapeutic substance(s).

248
~~11~~ (new): The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is administered in one or more dosage forms independently selected from the group consisting of chewable tablets, quick dissolve tablets, effervescent tablets, reconstitutable powders, elixirs, liquids, solutions, suspensions, emulsions, tablets, multi-layer tablets, bi-layer tablets, capsules, soft gelatin capsules, hard gelatin capsules, caplets,

lozenges, chewable lozenges, beads, powders, granules, particles, microparticles, dispersible granules, cachets, douches, suppositories, creams, topicals, inhalants, aerosol inhalants, patches, particle inhalants, implants, depot implants, ingestibles, injectables, infusions, health bars, confections, animal feeds, cereals, cereal coatings, foods, nutritive foods, functional foods, by a vaporizer and combinations thereof.

249

~~12~~ (new): The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is administered in two or more dosage forms independently selected from the group consisting of tablet, multi-layer tablet, capsule, or caplet.

250

~~13~~ (new): The drug delivery regimen of claim 1, wherein the multi-layer tablet is composed of an extended-release layer and an immediate release layer.

251

~~14~~ (new): The drug delivery regimen of claim 1, wherein the dosage form is coated for ease of administration, coated for delayed release or enteric coated to reduce gastric irritation.

252

~~15~~ (new): The drug delivery regimen of claim 1, wherein the dosage form is enteric coated and compressed into a tablet or filled into hard or soft gelatin capsules.

253
~~16~~ (new): The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is administered in uneven doses.

254
~~17~~ (new): The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is administered at uneven time intervals over the course of the 24 hour period.

255
~~18~~ (new): The drug delivery regimen of claim 1, wherein an AM dose and a PM dose are administered, and wherein the AM dose is larger or smaller than the PM dose.

256
~~19~~ (new): The drug delivery regimen of claim 1, wherein an AM dose and a PM dose are administered, and wherein the AM dose has a higher or lower amount of a water-soluble active therapeutic substance(s) present than that present in the PM dose.

257
~~20~~ (new): The drug delivery regimen of claim 1, wherein an AM dose and a PM dose are administered, and wherein the AM dosage has a higher or lower amount of a non water-soluble drug present than that present in the PM dosage.

258
~~21~~ (new): The drug delivery regimen of claim 1, wherein the dosage is adjusted for subsequent 24 hour periods of time.

259
~~22~~ (new): The drug delivery regimen of claim 1, wherein the

active therapeutic substance(s) is substituted for another active therapeutic substance(s).

260
~~23~~ (new): The drug delivery regimen of claim 1, wherein two PM doses are administered, and wherein the first PM dose is administered immediately after dinner and the second PM dose is administered immediately prior to bedtime.

261
~~24~~ (new): A drug delivery regimen, which comprises:
at least two doses of an active therapeutic substance(s) selected from the group consisting of a vitamin, a mineral, and combinations thereof administered during at least one 24 hour period of time to provide effective therapeutic levels of the active therapeutic substance(s) at a site or sites of action in an animal over said period, wherein the active therapeutic substance(s) is administered in uneven doses and over varying time intervals, and wherein the uneven doses and the varying time intervals are selected to optimize levels of the active therapeutic substance(s) at the site or sites of action for maximum efficacy.

262 261
~~25~~ (new): The drug delivery regimen of claim ~~24~~, wherein the vitamin is selected from the group consisting of thiamine, niacinamide, pyridoxine, ascorbic acid, riboflavin, folic acid, vitamin A, vitamin E, vitamin D3, cyanocobalamin, biotin, pantothenic acid, derivatives thereof, and combinations thereof.

263
~~26~~ (new): The drug delivery regimen of claim 261, ~~24~~, wherein the mineral is selected from the group consisting of copper, zinc, iodide, magnesium, chromium, molybdenum, sodium, calcium, iron, fluoride, phosphorus, manganese, potassium, boron, selenium, bioflavonoid, phosphate, derivatives thereof and combinations thereof.

264
27 (new): The drug delivery regimen of claim 261, ~~24~~, wherein the active therapeutic substance(s) is administered at least once and may be administered as immediate release, sustained release, controlled release, delayed release, timed release, extended release, or any combination thereof.

265
28 (new): The drug delivery regimen of claim 264, ~~27~~, wherein the active therapeutic substance(s) is administered by pulsatile delivery of the active therapeutic substance(s).

266
29 (new): The drug delivery regimen of claim 261, ~~24~~, wherein the active therapeutic substance(s) is administered in a dosage form independently selected from the group consisting of liquid, solution, suspension, emulsion, tablet, multi-layer tablet, capsule, soft gelatin capsule, caplet, lozenge, chewable lozenge, bead, powder, granules, dispersible granules, cachets, douche, suppository, cream, topical, inhalant, patch, particle inhalant,

implant, ingestible, injectable, infusion health bar, confection, animal feed, cereal, cereal coating, food, nutritive food, functional food, by a vaporizer and combinations thereof.

267 261
~~30~~ (new): The drug delivery regimen of claim ~~24~~, wherein the active therapeutic substance(s) is administered in a dosage form independently selected from the group consisting of tablet, multi-layer tablet, capsule, or caplet.

268 267
~~31~~ (new): The drug delivery regimen of claim ~~30~~, wherein the multi-layer tablet is composed of an extended-release layer and an immediate release layer.

269 267
~~32~~ (new): The drug delivery regimen of claim ~~30~~, wherein the dosage form is coated for ease of administration, coated for delayed release or enteric coated to reduce gastric irritation.

270 267
~~33~~ (new): The drug delivery regimen of claim ~~30~~, wherein the dosage form is enteric coated and compressed into a tablet or filled into hard or soft gelatin capsules.

271 261
~~34~~ (new): The drug delivery regimen of claim ~~24~~, wherein the active therapeutic substance(s)is administered in uneven doses.

272 261
~~35~~ (new): The drug delivery regimen of claim ~~24~~, wherein the

active therapeutic substance(s) is administered at uneven time intervals over the course of the 24 hour period.

273
~~36~~ (new): The drug delivery regimen of claim 261, wherein an AM dose and a PM dose are administered, and wherein the AM dose is larger or smaller than the PM dose.

274
~~37~~ (new): The drug delivery regimen of claim 261, wherein an AM dose and a PM dose are administered, and wherein the AM dose has a higher or lower amount of a water-soluble active therapeutic substance(s) is present than that present in the PM dose.

275
~~38~~ (new): The drug delivery regimen of claim 261, wherein an AM dose and a PM dose are administered, and wherein the AM dosage has a higher or lower amount of a non water-soluble drug present than that present in the PM dosage.

276
~~39~~ (new): The drug delivery regimen of claim 261, wherein the dosage is adjusted for subsequent 24 hour periods of time.

277
~~40~~ (new): The drug delivery regimen of claim 261, wherein the active therapeutic substance(s) is substituted for another active therapeutic substance(s).

278
~~41~~ (new): The drug delivery regimen of claim 261, wherein two

PM doses are administered, and wherein the first PM dose is administered immediately after dinner and the second PM dose is administered immediately prior to bedtime.

279
~~42~~ (new): A drug delivery regimen, which comprises: at least two doses of an active therapeutic substance(s) selected from the group consisting of a vitamin, a mineral, and combinations thereof is administered during at least one 24 hour period of time to provide effective therapeutic levels of the active therapeutic substance(s) at a site or sites of action in an animal over said period, and wherein each dose is independently calculated according to known pharmacokinetic parameters of the active therapeutic substance(s) with variations to account for physiological anomalies which occur during said period to optimize levels of the active therapeutic substance(s) at the site or sites of action for maximum efficacy.

280 279
~~43~~ (new): The drug delivery regimen of claim ~~42~~, wherein the vitamin is selected from the group consisting of thiamine, niacinamide, pyridoxine, ascorbic acid, riboflavin, folic acid, vitamin A, vitamin E, vitamin D3, cyanocobalamin, biotin, pantothenic acid, derivatives thereof, and combinations thereof.

281 279
~~44~~ (new): The drug delivery regimen of claim ~~42~~, wherein the mineral is selected from the group consisting of copper, zinc,

iodide, magnesium, chromium, molybdenum, sodium, calcium, iron, fluoride, phosphorus, manganese, potassium, boron, selenium, bioflavonoid, phosphate, derivatives thereof and combinations thereof.

282

~~45~~ (new): A method of enhancing the therapeutic effect of an active therapeutic substance(s) selected from the group consisting of a vitamin, a mineral, and combinations thereof in an animal, which comprises:

(a) determining known pharmacokinetic parameters of the active therapeutic substance(s);

(b) determining a number of doses to be administered during a 24 hour period of time and determining a time at which each dose will be administered by considering both the animal's schedule and physiological anomalies during the 24 hour period; and

(c) independently calculating the amount of each dose in accordance with the equation

$$TD(t) = CD(t) + RD(t)$$

where t is the time at which the dose is to be administered, TD (therapeutic dose) is the therapeutically effective dose at time (t), CD (current dose) is the dose to be administered at time (t), RD (residual dose) is the amount of active therapeutic substance(s) remaining from the previous dose

administration.

283
~~46~~ (new): The method of claim 282, ~~45~~, wherein the vitamin is thiamine, niacinamide, pyridoxine, ascorbic acid, riboflavin, folic acid, vitamin A, vitamin E, vitamin D3, cyanocobalamin, biotin, pantothenic acid, derivatives thereof and combinations thereof.

284 282
~~47~~ (new): The method of claim ~~46~~, wherein the mineral is selected from the group consisting of copper, zinc, iodide, magnesium, chromium, molybdenum, sodium, calcium, iron, fluoride, phosphorus, manganese, potassium, boron, selenium, bioflavonoid, phosphate, derivatives thereof and combinations thereof.

285 282
~~48~~ (new): The method of claim ~~45~~, wherein the active therapeutic substance(s) is administered at least twice and may be administered as immediate release, sustained release, controlled release, delayed release, timed release, extended release or any combination thereof.

286 282
~~49~~ (new): The method of claim ~~45~~, wherein the active therapeutic substance(s) is administered by pulsatile delivery of the active therapeutic substance(s).

287 282
~~50~~ (new): The method of claim ~~45~~, wherein the active therapeutic substance(s) is administered in a dosage form

independently selected from the group consisting of liquid, solution, suspension, emulsion, tablet, multi-layer tablet, capsule, gelatin capsule, caplet, lozenge, chewable lozenge, bead, powder, granules, dispersible granules, cachets, douche, suppository, cream, topical, inhalant, patch, particle inhalant, implant, ingestible, injectable, infusion, health bar, confection, animal feed, cereal, cereal coating, food, nutritive food, functional food, by a vaporizer and combinations thereof.

288 282
~~51~~ (new): The method of claim ~~45~~, wherein the active therapeutic substance(s) is administered in a dosage form independently selected from the group consisting of a tablet, multi-layer tablet, capsule and caplet.

289 282
~~52~~ (new): The method of claim ~~45~~, wherein the active therapeutic substance(s) is administered in uneven doses.

290 282
~~53~~ (new): The method of claim ~~45~~, wherein the active therapeutic substance(s) is administered at uneven time intervals over the course of the 24 hour period.

291 282
~~54~~ (new): The method of claim ~~45~~, wherein an AM dose and a PM dose are administered, and wherein the AM dose is larger or smaller than the PM dose.

292 ~~55~~ (new): The method of claim 282 ~~45~~, wherein an AM dose and a PM dose are administered, and wherein the AM dose has a higher or lower amount of a water-soluble active therapeutic substance(s) present than that present in the PM dose.

293 ~~56~~ (new): The method of claim 282 ~~45~~, wherein an AM dose and a PM dose are administered, and wherein the AM dosage has a higher or lower amount of a non water-soluble drug present than that present in the PM dosage.

294 ~~57~~ (new): The method of claim 282 ~~45~~, wherein the dosage is adjusted for subsequent 24 hour periods of time.

295 ~~58~~ (new): The method of claim 282 ~~45~~, wherein the active therapeutic substance(s) is substituted for another active therapeutic substance(s).

296 ~~59~~ (new): The method of claim 282 ~~45~~, wherein two PM doses are administered, and wherein the first PM dose is administered immediately after dinner and the second PM dose is administered immediately prior to bedtime.

297 ~~60~~ (new): A pharmaceutical composition for optimizing therapeutic activity, which comprises:

a first active therapeutic substance(s) selected from the

group consisting of water-soluble vitamins and water -soluble minerals; and

a second active therapeutic substance(s) selected from the group consisting of non water-soluble vitamins and non water-soluble minerals;

wherein the ratio of the first active therapeutic substance(s) to the second active therapeutic substance(s) is independently tailored to optimize levels of the respective active therapeutic substances at a site or sites of action in an animal for maximum efficacy, and wherein said weight ratio is determined according to the time at which said composition is to be administered with a suitable pharmaceutical carrier.

298 ~~61~~ (new): The pharmaceutical composition of claim 297 ~~60~~, wherein the water-soluble vitamin is selected from the group consisting of vitamin B_1, vitamin B_2, vitamin B_3, biotin, pantothenic acid, vitamin B_6, folate, vitamin B_{12}, vitamin C, derivatives thereof and combinations thereof.

299 ~~62~~ (new): The pharmaceutical composition of claim 297 ~~60~~, wherein the water-soluble mineral is selected from the group consisting of sodium, potassium, calcium, phosphorus, magnesium, sulfur, ferrous iron, zinc, iodide, copper, fluoride, derivatives thereof and

combinations thereof.

300 297

~~63~~ (new): The pharmaceutical composition of claim ~~60~~, wherein the non water-soluble vitamin is selected from the group consisting of vitamin A, vitamin D, vitamin E, vitamin K, derivatives thereof and combinations thereof.

301 297

~~64~~ (new): The pharmaceutical composition of claim ~~60~~, wherein the non water-soluble mineral is selected from the group consisting of chromium, ferric iron, molybdenum, selenium, derivatives thereof and combinations thereof.